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Implants, and Musculoskeletal Transplant
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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

NUVASIVE, INC. and
OSIRIS THERAPEUTICS, INC.,

Plaintiffs/Counterclaim Defendants,

v.

ORTHOFIX INTERNATIONAL N.V.,
ORTHOFIX, INC., ORTHOFIX HOLDINGS,
INC., ORTHOFIX BIOLOGICS,
ORTHOFIX SPINAL IMPLANTS, and
MUSCULOSKELETAL TRANSPLANT
FOUNDATION,

Defendants/Counterclaim Plaintiffs.

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No. 2:10-cv-01995-SDW -MCA

**ANSWER, AFFIRMATIVE
DEFENSES AND
COUNTERCLAIMS OF ORTHOFIX
INTERNATIONAL N.V.,
ORTHOFIX, INC., ORTHOFIX
HOLDINGS, INC., ORTHOFIX
BIOLOGICS, AND ORTHOFIX
SPINAL IMPLANTS**

JURY TRIAL DEMANDED

ANSWER

Defendants/Counterclaim Plaintiffs Orthofix International N.V., Orthofix Inc., Orthofix Holdings, Inc., Orthofix Biologics, and Orthofix Spinal Implants (collectively, "Orthofix"),

through their undersigned counsel, hereby answer the complaint for patent infringement filed by Plaintiffs/Counterclaim Defendants NuVasive, Inc. and Osiris Therapeutics, Inc. (collectively, “Plaintiffs”), in accordance with the numbered paragraphs thereof, as follows:

NATURE OF THE ACTION

1. Orthofix admits that Plaintiffs have filed an action for patent infringement and have attached a copy of U.S. Patent No. 6,335,239 (“the 239 patent”) as Exhibit A to the complaint. Orthofix denies any infringement of the 239 patent.

2. Orthofix admits that the 239 patent lists Osiris Therapeutics, Inc. of Baltimore, Maryland as an assignee. Orthofix is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in paragraph 2 of the complaint and, on that basis, denies the same.

3. Orthofix admits that in 2008, NuVasive purchased the OsteoCel® product line from Osiris for \$85 million. Orthofix is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in paragraph 3 of the complaint and, on that basis, denies the same. By way of further answer, Orthofix avers that, before NuVasive’s purchase of the OsteoCel® product line, Osiris informed Blackstone Medical, Inc. (“Blackstone”) that there was no issued patent covering the OsteoCel® product line and therefore that the 239 patent was inapplicable to the OsteoCel® product line.

4. Denied as stated. By way of further answer, Orthofix avers that Blackstone is a wholly-owned subsidiary of Orthofix Holdings, Inc, and that Blackstone distributed OsteoCel® under the trade name Trinity® pursuant to a Distribution and Supply Agreement with Osiris dated November 10, 2005 (the “Osiris Agreement”), which provided (a) that Blackstone would be the exclusive spinal implant distributor of OsteoCel® in the United States for the term of the Osiris Agreement, (b) that the initial term of the Osiris Agreement would

run through December 31, 2008, with the option to renew for successive one year terms, and (c) that disputes arising out of the Osiris Agreement would, if unresolved by private negotiations, be submitted to binding arbitration. Orthofix further avers that in May 2008, NuVasive, a competing spinal implant manufacturer, announced that it had entered into an agreement to purchase the OsteoCel® product line from Osiris, with closing to take place at a later date in 2008. Orthofix further avers that shortly thereafter, NuVasive announced to Blackstone that it would begin selling OsteoCel® in the United States in 2008, *i.e.*, before the end of Blackstone's initial term of exclusive distribution for spinal implant applications in the United States expired on December 31, 2008. Orthofix further avers that in July 2008, shortly before the date on which Osiris had announced its plans to close on the OsteoCel® purchase agreement with NuVasive, and because of NuVasive's statements that it intended to start sale of OsteoCel® in 2008 before the end of Blackstone's initial term of exclusivity under the Osiris Agreement, Blackstone filed a lawsuit in the United States District Court for the District of Massachusetts (Civ. A. 3:08-cv-30145-MAP) seeking *inter alia* a temporary restraining order and preliminary injunction to enjoin closing of the sale so that Blackstone's dispute could be arbitrated pursuant to the terms of the Osiris Agreement. Orthofix further avers that Blackstone voluntarily dismissed its lawsuit against Osiris in September 2008, after NuVasive made assurances to Orthofix, and to the District Court, that NuVasive, even after closing of its purchase of the OsteoCel® product line, would continue to operate under the Osiris Agreement through the end of the initial term ending December 31, 2008. Orthofix further avers that NuVasive declined to renew the Osiris Agreement after the end of the initial term.

5. Denied. By way of further answer, Orthofix avers that the Musculoskeletal Transplant Foundation ("MTF") had started its own research and development program in

2006 to develop an allograft tissue form that included MSCs, now known as Trinity Evolution, and that Orthofix agreed to collaborate with MTF to commercialize the Trinity Evolution tissue form. Orthofix denies any infringement of the 239 patent, and further avers that, before NuVasive's purchase of the OsteoCel® product line, Osiris informed Blackstone that there was no issued patent covering the OsteoCel® product line and therefore that the 239 patent was inapplicable to the OsteoCel® product line.

6. Orthofix admits that Plaintiffs' complaint seeks injunctive relief and damages for alleged infringement of the 239 patent. Orthofix denies the remaining allegations set forth in paragraph 6 of the complaint, and denies any infringement of the 239 patent.

THE PARTIES

7. Orthofix is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 7 of the complaint and, on that basis, denies the same.

8. Orthofix is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 8 of the complaint and, on that basis, denies the same.

9. Orthofix admits that Orthofix International N.V. is incorporated under the laws of the Netherlands Antilles with United States corporate headquarters at 800 Boylston Street, Boston, Massachusetts 02199, and that Orthofix International N.V. has carried out some business in New Jersey. Orthofix denies the remaining allegations set forth in paragraph 9 of the complaint, and denies any infringement, inducement of infringement, or contributory infringement of the 239 patent.

10. Orthofix admits that Orthofix Inc. is incorporated under the laws of the State of Minnesota with a principal place of business at 1720 Bray Central Drive, McKinney, Texas

75069. Orthofix Inc. has carried out some business in New Jersey. Orthofix denies the remaining allegations set forth in paragraph 10 of the complaint, and denies any infringement, inducement of infringement, or contributory infringement of the 239 patent.

11. Orthofix admits that Orthofix Holdings, Inc. is incorporated under the laws of the State of Delaware with a principal place of business at 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808, and that Orthofix Holdings, Inc. has carried out some business in New Jersey. Orthofix denies the remaining allegations set forth in paragraph 11 of the complaint, and denies any infringement, inducement of infringement, or contributory infringement of the 239 patent.

12. Orthofix admits that Blackstone Medical, Inc. is incorporated under the laws of the States of Massachusetts with a principal place of business at 1720 Bray Central Drive, McKinney, Texas 75069, that Blackstone Medical, Inc. has carried out some business in New Jersey, and that Orthofix Spinal Implants and Orthofix Biologics are names under which Blackstone Medical, Inc. does business. Orthofix denies the remaining allegations set forth in paragraph 12 of the complaint, and denies any infringement, inducement of infringement, or contributory infringement of the 239 patent.

13. Orthofix admits that MTF has offices at 125 May Street, Edison, New Jersey 08837. Orthofix denies the remaining allegations set forth in paragraph 13 of the complaint, and denies any infringement, inducement of infringement, or contributory infringement of the 239 patent.

JURISDICTION AND VENUE

14. Paragraph 14 states a legal conclusion to which no answer is required. By way of further answer, Orthofix does not contest this Court's subject matter jurisdiction over this action.

15. Paragraph 15 states a legal conclusion to which no answer is required. By way of further answer, Orthofix does not contest personal jurisdiction in New Jersey solely for purposes of this action.

16. Paragraph 16 states a legal conclusion to which no answer is required. By way of further answer, Orthofix does not contest venue in this District solely for purposes of this action.

THE PATENT-IN-SUIT AND SUBJECT MATTER CLAIMS

17. Orthofix admits that the 239 patent is entitled “Uses for Non-Autologous Mesenchymal Stem Cells” and that the 239 patent bears the issue date of March 12, 2002. Orthofix is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in paragraph 17 of the complaint and, on that basis, denies the same.

18. Orthofix admits that the 239 patent purports to claim a method for treating a human subject for promoting connective tissue growth, comprising treating a recipient human subject in need of connective tissue growth by administering a therapeutically effective amount of allogeneic mesenchymal stem cells to said recipient human subject, wherein said allogeneic mesenchymal stem cells are obtained from a donor human subject and wherein a step of MHC matching of said donor human subject to said recipient human subject is not employed prior to the administration of said allogeneic mesenchymal stem cells to the recipient human subject. Orthofix is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in paragraph 18 of the complaint and, on that basis, denies the same.

19. Admitted.

20. Admitted.

21. Admitted.

22. Denied as stated. By way of further answer, Orthofix avers that in some instances, autologous transplants present a lower risk of rejection than allogeneic transplants, but that allogeneic transplants have also been performed without rejection.

23. Admitted.

24. Denied.

25. Denied.

26. Denied.

DEFENDANTS' ALLEGED WILLFUL INFRINGEMENT OF THE 239 PATENT

27. Orthofix is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 27 of the complaint and, on that basis, denies the same.

28. Orthofix admits that the 239 patent bears the issue date of March 12, 2002. Orthofix is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in paragraph 28 of the complaint and, on that basis, denies the same.

29. Orthofix is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 29 of the complaint and, on that basis, denies the same.

30. Denied as stated. By way of further answer, Orthofix avers that Blackstone entered into the Osiris Agreement on November 10, 2005, not March 2006 as alleged in paragraph 30 of the complaint, and lawfully distributed OsteoCel® under the trade name Trinity® pursuant to that agreement.

31. Denied as stated. By way of further answer, Orthofix avers that Blackstone was acquired in September 2006 by Orthofix International, N.V. Orthofix denies that it or Blackstone promoted the Trinity® product line specifically because it failed to prove a significant immunogenic response upon implantation.

32. Denied as stated. By way of further answer, Orthofix avers that Osiris decided to divest the Osteocel® product line in early 2007; that Blackstone first investigated purchasing the Osteocel® line of business from Osiris in 2007; but that Blackstone determined that it was overvalued, in part based Osiris' representations to Blackstone at the time that there was no issued patent covering the OsteoCel® product line and that the 239 patent was inapplicable to the OsteoCel® product line. Orthofix further avers that Blackstone did not lose its distribution rights to the Trinity® product line by virtue of the sale of the OsteoCel® product line to NuVasive. To the contrary, both NuVasive and Osiris made assurances to Blackstone, and to the United States District Court for the District of Massachusetts, that NuVasive would continue to operate under the Osiris Agreement even after NuVasive's purchase of the OsteoCel® product line closed.

33. Denied as stated. By way of further answer, Orthofix avers that Blackstone filed its lawsuit and request for a temporary restraining order and preliminary injunction in the United States District Court for the District of Massachusetts on July 23, 2008, not September 2008, as alleged in paragraph 33 of the complaint. Orthofix further avers that Blackstone filed this lawsuit at that time because the Osiris Agreement provided that Blackstone would be the exclusive spinal implant distributor of OsteoCel® in the United States for the term of the Osiris Agreement, which would run through at least December 31, 2008, but NuVasive, a competing spinal implant manufacturer, announced to Blackstone that, after closing on the OsteoCel®

purchase, NuVasive would begin selling OsteoCel® in the United States in 2008, *i.e.*, before the end of Blackstone's initial term of exclusive distribution for spinal implant applications in the United States expired on December 31, 2008. Orthofix further avers the District Court denied Blackstone's request for relief based on assurances from NuVasive and Osiris that NuVasive, even after the closing of its purchase of the OsteoCel® product line, would continue to operate under the Osiris Agreement through at least December 31, 2008. Specifically, the District Court stated the following at the July 24, 2008 hearing on Blackstone's motion for relief (Dkt. 21 at p. 23, in *Blackstone Med'l, Inc. v. Osiris Therapeutics, Inc.*, 3:08-cv-30145-MAP, D. Mass):

So based upon the representations that I have just heard, I'm going to deny plaintiff's motion for temporary relief. It is on condition that if the sale goes forward, the purchaser [NuVasive] will comply fully with the provisions of the applicable agreement through the end of December 2008, and I understand that is fully the intention both of the seller Osiris here and of the third party [purchaser] NuVasive.

Orthofix further avers that Blackstone voluntarily dismissed its lawsuit against Osiris in September 2008, based upon the assurances that NuVasive made to Blackstone (and to the District Court), and not because of any purported violation of the Osiris Agreement by Blackstone, as alleged in paragraph 33 of the complaint.

34. Denied. By way of further answer, Orthofix avers that MTF started its own research and development program in 2006 to develop an allograft tissue form that included MSCs, now known as Trinity Evolution, and that Orthofix agreed to collaborate with MTF to commercialize the Trinity Evolution tissue form. Orthofix denies any infringement of the 239 patent, and further avers that, before NuVasive's purchase of the OsteoCel® product line, Osiris informed Blackstone that there was no issued patent covering the OsteoCel® product line and that the 239 patent was inapplicable to the OsteoCel® product line.

COUNT I – PATENT INFRINGEMENT

35. Denied as stated. By way of further answer, Orthofix avers that MTF processes the allograft tissue form Trinity Evolution, and that Orthofix markets the Trinity Evolution tissue form.

36. Denied.

37. Denied.

38. Denied.

39. Denied.

COUNT II – DECLARATORY JUDGMENT OF PATENT INFRINGEMENT

40. Denied as stated. By way of further answer, Orthofix avers that MTF processes the tissue form Trinity Evolution, and that Orthofix markets the Trinity Evolution tissue form.

41. Denied.

42. Denied.

43. Denied.

44. Denied.

45. Denied.

PRAYER FOR RELIEF

Orthofix denies that Plaintiffs are entitled to any of the relief sought.

FIRST AFFIRMATIVE DEFENSE

The complaint fails to state a claim against Orthofix upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

Orthofix has not infringed, and is not infringing, directly or indirectly, any valid and enforceable claim of the 239 patent.

THIRD AFFIRMATIVE DEFENSE

One or more claims of the 239 patent are invalid under one or more of 35 U.S.C. §§ 101, 102, 103, and 112.

FOURTH AFFIRMATIVE DEFENSE

The claims in the 239 patent are so limited by prior art, by their terms, and by the prosecution in the United States Patent & Trademark Office of the applications upon which the 239 patent issued, including by estoppel based on that prosecution, that none of the claims is infringed.

COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Defendants/Counterclaim Plaintiffs Orthofix, for its counterclaims against Plaintiffs/Counterclaim Defendants NuVasive, Inc. and Osiris Therapeutics, Inc. (collectively, "Counterclaim Defendants"), allege as follows:

PARTIES

1. Orthofix International N.V. is incorporated under the laws of the Netherlands Antilles with United States corporate headquarters at 800 Boylston Street, Boston, Massachusetts 02199.

2. Orthofix Inc. is incorporated under the laws of the State of Minnesota with a principal place of business at 1720 Bray Central Drive, McKinney, Texas 75069.

3. Orthofix Holdings, Inc. is incorporated under the laws of the State of Delaware with a principal place of business at 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808.

4. Blackstone Medical, Inc. is incorporated under the laws of the States of Massachusetts with a principal place of business at 1720 Bray Central Drive, McKinney, Texas 75069. Orthofix Spinal Implants and Orthofix Biologics are names under which Blackstone Medical, Inc. does business.

5. Musculoskeletal Transplant Foundation is a non-profit service organization organized under the laws of the State of New Jersey with offices at 125 May Street, Edison, New Jersey 08837.

6. NuVasive, Inc. alleges that it is incorporated under the laws of the State of Delaware with its principal place of business at 7475 Lusk Boulevard, San Diego, California 92121.

7. Osiris Therapeutics, Inc. alleges that it is incorporated under the laws of the States of Delaware with its principal place of business at 7015 Albert Einstein Drive, Columbia, Maryland 21046.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

9. This Court has personal jurisdiction over Counterclaim Defendants because, among other reasons, they have availed themselves of this Court to sue Orthofix in this action.

10. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and 1391(c).

COUNT I – DECLARATORY JUDGMENT OF NON-INFRINGEMENT

11. Orthofix repeats, realleges, and incorporates by reference, the allegations in paragraphs 1 through 45 of its answer to the complaint and paragraphs 1 through 10 of these counterclaims as if fully set forth herein.

12. The 239 patent was apparently issued, albeit improperly, by the United States Patent & Trademark Office on March 12, 2002. Osiris claims to be the owner of the 239 patent.

13. Counterclaim Defendants have alleged that certain acts by Orthofix infringe the 239 patent.

14. An actual controversy exists between Orthofix and Counterclaim Defendants regarding the validity and infringement of each claim of the 239 patent.

15. Orthofix has not infringed and is not infringing, either directly or indirectly, any valid and enforceable claim of the 239 patent.

16. A judicial determination is necessary and appropriate so that Orthofix by ascertain its rights regarding the 239 patent.

COUNT II – DECLARATORY JUDGMENT OF INVALIDITY

17. Orthofix repeats, realleges, and incorporates by reference, the allegations in paragraphs 1 through 45 of its answer to the complaint and paragraphs 1 through 16 of these counterclaims as if fully set forth herein.

18. The 239 patent is invalid for failure to satisfy one or more conditions of patentability set forth in Title 35 of the United States Code, including but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112.

19. A judicial declaration is necessary and appropriate so that Orthofix may ascertain its rights regarding the 239 patent.

EXCEPTIONAL CASE

20. On information and belief, this is an exceptional case entitling Orthofix to an award of its attorneys' fees incurred in connection with defending and prosecuting this action pursuant to 35 U.S.C. § 285, as a result of, *inter alia*, Counterclaim Defendants' assertion of the 239 patent against Orthofix with the knowledge that Orthofix does not infringe any valid claim of the 239 patent and/or that the patent is invalid.

RELIEF REQUESTED

WHEREFORE, Orthofix respectfully requests the following relief:

- A. A judgment in favor of Orthofix denying Plaintiffs/Counterclaim Defendants all relief requested in this action and dismissing the complaint with prejudice;
- B. A judgment declaring that each claim of the 239 patent is invalid;
- C. A judgment declaring that Orthofix has not infringed and is not infringing any valid claim of the 239 patent, and that Orthofix has not contributed to or induced, and is not contributing to or inducing, infringement of any valid and enforceable claim of the 239 patent;
- D. A judgment declaring this to be an exceptional case under 35 U.S.C. § 285 and awarding to Orthofix its costs, expenses, and reasonable attorneys' fees; and
- E. An award to Orthofix of such other and further relief as the Court deems just and proper.

JURY DEMAND

Pursuant to Fed. R. Civ. P. 38(b), Orthofix hereby demands a trial by jury on all issues so triable.

Dated: June 8, 2010
New York, New York

Respectfully submitted,

s/ David J. Sheehan
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Plaintiffs Orthofix International N.V.,
Orthofix Inc., Orthofix Holdings, Inc.,
Orthofix Biologics, Orthofix Spinal
Implants, and Musculoskeletal Transplant
Foundation*

RULE 11.2 INITIAL CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify, to the best of my knowledge, that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: June 8, 2010
New York, New York

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NUVASIVE, INC. and OSIRIS THERAPEUTICS, INC.,

Plaintiffs

v.

ORTHOFIX INTERNATIONAL N.V., et al

Defendants

Docket No. 10-cv-01995 (SDW)
(MCA)

CERTIFICATE OF SERVICE

I, Jason S. Oliver, hereby certify that on this 8th day of June, 2010, I caused a true and correct copy of the foregoing Answer, Affirmative Defenses and Counterclaims of Defendants Orthofix International N.V., Orthofix, Inc., Orthofix Holdings, Inc., Orthofix Biologics and Orthofix Spinal Implants to be served by e-mail and CM/ECF (for those registered) on the following:

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